DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 15, 2015

Teleflex Medical, Inc.
Lori Pfohl
Senior Regulatory Affairs Specialist
2917 Weck Dr.
Research Triangle Park, NC 27709

Re: K141888
Trade/Device Name: Rusch Endobronchial Tubes
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: March 13, 2015
Received: March 16, 2015

Dear Ms. Pfohl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K141888

Device Name
Rusch Endobronchial Tubes

Indications for Use *(Describe)*

Rusch Endobronchial Tubes are used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

Patient Population: Patients requiring one lung isolation

Environment of use: Hospitals – OR and ICU

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY
March 4, 2015

Name, Address, Phone and Fax Number of Applicant

Teleflex Medical, Incorporated
2917 Weck Drive
Research Triangle Park, NC 27709 USA
Phone: 919-491-8960
Fax: 919-433-4996

Contact Person

Lori Pfohl
Senior Regulatory Affairs Specialist

Device Name

Trade Name: Rusch Endobronchial Tubes

Common Name: Bronchial Tube

Classification Name: Tube, Trachael/Bronchial, Differential Ventilation (w/wo connector) (Class II per 21 CFR 868.5740, Product Code CBI)

Predicate Devices

K051522 Silbroncho Double Lumen Tube
K092886 Well Lead Endobronchial Tubes

Device Description

The Rusch Endobronchial Tube is a sterile, single patient use PVC Double-Lumen Endobronchial Tube (also referred to as a DLT) that is inserted into the trachea via the mouth in order to selectively ventilate one lung. The Endobronchial tube is sold with or without accessories, contains a stylet and is available in Robertshaw, Carlens and White styles.

Intended Use

Rusch Endobronchial Tubes are used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

Patient Population: Patients requiring one lung isolation

Environment of use: Hospitals – OR and ICU

Contraindications

Left sides versions are contraindicated in patients with obstructions or stenosis in the left main bronchus. The right sided versions are contraindicated in patients with obstructions or stenosis in the right main bronchus. The versions with a carina hook are contraindicated for all procedures in the region of the carina.

Substantial Equivalence Comparison to Predicates

The proposed device is substantially equivalent to the predicate devices:

Features	Teleflex Medical Endobronchial Tube (proposed)	Fuji Systems Silcobronch (K051522)	Well Lead EndobronchialTube (K092886)
Classification Name	Tube, Trachael/Bronchial, Differential Ventilation (w/wo connector)	Same	Same
Product Code	CBI	Same	Same
Regulation Number	868.5740	Same	Same
Indications for Use	Rusch Endobronchial Tubes are used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia	Same	Same
Environment of Use	Hospital – OR and ICU	Same	Not stated
Patient Population	Patients requiring one lung isolation	Same	Not stated
Contraindications	Left sides versions are contraindicated in patients with obstructions or stenosis in the left main bronchus. The right sided versions are contraindicated in patients with obstructions or stenosis in the right main bronchus. The versions with a carina hook are contraindicated for all procedures in the region of the carina	Not Stated	Not Stated
Design Features	Double lumen shaft, 2 cuffs, Stylet	Same	Same
Single Use	Yes	Same	Same
Size Range	26-41 French	33-39 French	28-41 French
Cuffed	Yes	Same	Same
Radiopaque	Yes	No	Yes
Connection to ventilation source	15 mm connector	Same	Same
DLT Materials	PVC	Silicone	PVC

- **Indications for Use** – The indications for use are identical for the proposed device when compared to the predicates. Each device is used to isolate the left or right lung of a patient for surgery, one lung ventilation or one lung anesthesia.

- **Technology and construction** - The design, fabrication, shape, size, etc. are equivalent to the predicates. The designs of the propose and predicate devices consist a double lumen tube with

cuffs on each lumen, and corresponding side arm assemblies to inflate the cuffs.

- **Environment of use** – Identical to predicate. Hospital – OR and ICU
- **Patient Population** – Identical to predicate. Patients requiring one lung isolation
- **Materials** -All patient contacting materials are in compliance with ISO 10993-1. Testing included cytotoxicity, sensitization and intracutaneous activity.

Comparison to Predicate Device:

The proposed **Endobronchial** tubes are substantially equivalent to the predicate devices with respect to indications for use, technology and construction. The differences between the predicate and the proposed devices are minor and any risks have been mitigated through testing. Additionally, the proposed device is made with the same materials as the K092886 predicate.

Non-clinical Comparative Performance Testing

A brief summary of tests relied upon to demonstrate substantial equivalence to the predicate can be found in the table below:

Test	Reference to Standard (if applicable)	Principle of Test
Connector bonding strength	ISO 5356	The security of the attachment of the connector to the Endobronchial tube is tested by applying an axial separation force to the connector
Cuff resting diameter	ISO 5361	The resting diameter of the cuff is measured when the cuff is inflated to a reference pressure which is intended to remove creases but minimize stretching of its walls
Tube collapse	ISO 5361	The patency of the Endobronchial tube airway lumen is tested by passing a steel ball through the Endobronchial tube lumen with the cuff inflated within a transparent tube
Cuff herniation	ISO 5361	The tendency of the cuff to herniate beyond the plane perpendicular to the long axis of the tube at the nearest edge of the bevel is tested by applying an axial force with the cuff inflated within a transparent tube. A cuff which protrudes excessively at its patient end may partially or completely occlude the orifice at the patient end
Cuff Burst Evaluation	N/A	The cuff restrained burst test is designed to ensure the cuff will not burst or rupture when inflated inside the trachea
Cuff Bond Strength	N/A	To evaluate the strength needed to separate the cuff from the tube
Side arm bonding strength	N/A	To evaluate the retention force of the inflation line connection to the Endobronchial tube

Substantial Equivalence Conclusion

The **Rusch Endobronchial Tubes** have the same indications for use, patient population and technology of construction as the predicate devices. Performance test results demonstrate that the proposed device meets its intended use. It is for these reasons that the proposed device can be found substantially equivalent.